

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

SHIRAL STIDHAM,

Plaintiff,

v.

Case No. 1:08-cv-3387-PKC

GENERAL ELECTRIC COMPANY,  
GE HEALTHCARE, INC., and  
GE HEALTHCARE AS,

Defendants.

<b>COMPLAINT AND JURY DEMAND</b>
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Plaintiff, Shiral Stidham by and through her attorney, The Levensten Law Firm,  
P.C., and for her Complaint and Jury Demand against Defendants, alleges as follows:

**PARTIES, VENUE AND JURISDICTION**

1. Plaintiff Shiral Stidham is a resident and citizen of Fort Worth, located in Tarrant County, Texas.
2. Plaintiff alleges an amount in controversy in excess of Seventy Five Thousand Dollars (\$75,000.00), exclusive of interest and costs.
3. Defendant General Electric Company is a New York corporation with its principal place of business at 3135 Easton Turnpike, Fairfield, Connecticut 06431. Defendant General Electric Company is a resident and citizen of both New York and Connecticut. Defendant General Electric Company is the parent company of Defendant GE Healthcare, Inc. and Defendant GE Healthcare AS.

4. At all times relevant, Defendant General Electric Company was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Omniscan.

5. Defendant GE Healthcare, Inc. is a Delaware corporation with its principal place of business at 101 Carnegie Center, Princeton, New Jersey. Defendant GE Healthcare, Inc. is a resident and citizen of both Delaware and New Jersey. Defendant GE Healthcare, Inc. is a subsidiary of General Electric Company.

6. At all times relevant, Defendant GE Healthcare, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Omniscan.

7. Defendant GE Healthcare AS is a Norwegian corporation with its principal place of business in Norway. Defendant GE Healthcare AS is a subsidiary of General Electric Company.

8. At all times relevant, Defendant GE Healthcare AS was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the drug Omniscan.

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

10. The Court has personal jurisdiction over Defendants consistent with New York Law and the United States Constitution because of Defendants' regularly conducted business in New York from which they derive substantial revenue.

11. Venue in this district is appropriate under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in the district.

**OMNISCAN (GADODIAMIDE) AND PLAINTIFF'S INJURIES**

12. Omniscan is an injectable paramagnetic contrast agent for magnetic resonance imaging and arteriography. It contains the metal gadolinium which is highly toxic in its free state. Omniscan, the chemical name of which is gadolinium diethylenetriamine pentaacetic acid bismethylamide (gadodiamide), is represented by Defendants to be safely and effectively indicated for intravenous administration to facilitate the visualization of lesions with abnormal vascularity.

13. Omniscan (gadodiamide) was originally developed in the early 1990s by Salutar, Inc. which subsequently transferred the rights to Omniscan to Sterling Winthrop, a subsidiary of Eastman Kodak Company.

14. In 1994, the diagnostic imaging division of Sterling Winthrop, which held the rights to Omniscan, was sold to Hafslund Nycomed AS, a Norwegian company.

15. In 1997, Nycomed merged with Amersham International, a British company, and the resulting entity that held the rights to Omniscan was Amersham PLC.

16. In January 2004, Defendant General Electric purchased Amersham PLC, combined it with its own GE Medical Systems, and created a new subsidiary called GE Healthcare, Inc.

17. Omniscan is cleared from the body by glomerular filtration in the kidneys. As a result, it has a prolonged half-life in patients with renal insufficiency and who, therefore, are at increased risk for adverse health effects in connection with Omniscan administration.

18. In pre-clinical safety assessment during which Omniscan was injected into laboratory animals, consistent patterns of toxicity including nephrogenic fibrotic changes in the skin and other body organs occurred.

19. Despite these nephrogenic fibrotic changes and other data warranting caution and further evaluation, Omniscan was marketed and sold without appropriate clinical evaluation of the nephrotoxic effect of this drug on patients with renal insufficiency, without appropriate clinical evaluation of the propensity of this drug to produce nephrogenic fibrosis in humans, and without appropriate and effective warning with respect to either.

20. At all times relevant hereto, Defendants knew or should have known about the significant health risk of Omniscan administration to patients with renal insufficiency, including, but not limited to, the risk of nephrogenic fibrosis in the skin and other body organs.

21. Nephrogenic Systemic Fibrosis (NSF), also known as Nephrogenic Fibrosing Dermopathy (NSD), has been reported in medical literature for at least the last decade.

22. Prior to a decade ago, the group of symptoms now known as NSF/NSD had been variously described as scleromyxedema, scleroderma, or other connective tissue diseases. Regardless of the name ascribed to it, however, it has always been the case that this

clinical entity now known as NSF/NSD develops only in patients with renal insufficiency who have been given an injection of gadolinium-type contrast agent such as Omniscan.

23. While there are gadolinium-type paramagnetic contrast agents available for administration in the United States, greater than 90% of all patients who have been diagnosed with NSF/NSD have received injections of Omniscan in connection with magnetic resonance imaging or arteriography.

24. Omniscan is chemically distinct from other gadolinium-type contrast agents, in that it carries no molecular charge and is arranged in a linear structure with excess chelate such that it permits the release of free gadolinium ions and the extravasations of toxic gadolinium.

25. NSF/NSD is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin within days or weeks after receiving an Omniscan injection. These fibrotic and edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in contractures. NSF/NSD often progresses to painful inhibition of the ability to use the arms, legs, hands, feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a “woody” texture and are accompanied by burning, itching, or severe pain in the areas of involvement. NSF/NSD also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart, liver, and musculature, and that can inhibit their ability to function properly and may lead to death. NSF/NSD is a progressive disease as to which there is no known cure.

26. The Defendants have consistently failed to warn consumers and/or their health care providers that NSF/NSD could result when Omniscan is administered to patients with renal insufficiency.

27. During the years that Defendants have manufactured, marketed, and sold Omniscan, there have been numerous case reports, studies, assessments, papers, and other clinical data that have described and/or demonstrated NSF/NSD in connection with the use of Omniscan. Despite this, Defendants have repeatedly failed to revise their package inserts, Material Safety Data Sheets, and other product-related literature, and to conduct appropriate post-marketing communications in order to convey adequate warnings.

28. In June 2006, and again in updated form in December 2006, the FDA issued Public Health Advisory Alerts concerning the development of serious, sometimes fatal, NSF/NSD following exposure to gadolinium-based contrast agents, including Omniscan.

29. The Defendants have repeatedly and consistently failed to advise consumers and/or their health care providers of the causal relationship between Omniscan and NSF/NSD in patients with renal insufficiency.

30. The Defendants have failed to take prompt, reasonable, and effective measures to alert the appropriate members of the health care community and its patients, including, but not limited to, renal patients, nephrologists and other physicians, radiologists, administrators, technicians, and hospital/radiology supply personnel, to the serious adverse health risks presented by Omniscan administration.

31. As a result of Defendants' claim regarding the safety and effectiveness of Omniscan, Plaintiff, in the course of a post renal transplant follow-up, was administered Omniscan on or about April, 2005, in connection with magnetic resonance angiography (MRA) at Harris Methodist Fort Worth, Fort Worth, Texas.

32. Neither Plaintiff, nor her prescribing physician, nor the performing radiologists or technicians were warned or cautioned by Defendants about the serious health risks presented by the administration of Omniscan.

33. Subsequent to being administered Omniscan, Plaintiff developed NSF/NFD, which was formally diagnosed, and which has progressed to widespread fibrosis and edema in areas including, but not limited to, her arms, legs, and associated joints. Plaintiff experiences burning, itching and severe pain across her affected areas.

34. As a direct and proximate result of being administered Omniscan, Plaintiff suffers serious, progressive, incurable, and potentially fatal injuries.

35. Prior to April 2005, Defendants knew or should have known that the administration of Omniscan to patients with renal insufficiency created an increased risk to those consumers of serious personal injury and even death.

36. Therefore, at the time Plaintiff was administered Omniscan in April 2005, Defendants knew or should have known that the use of Omniscan created an increased risk of serious personal injury, or even death to consumers with renal insufficiency.

37. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Omniscan, Defendants failed to warn Plaintiff and/or her health care providers of those serious risks.

38. Had Plaintiff and/or her health care providers known the risks of damages associated with Omniscan she would not have been administered Omniscan and would not have been afflicted with NSF/NSD.

39. As a direct and proximate result of Plaintiff's being administered Omniscan, she has suffered significant harm, conscious pain and suffering, physical injury and bodily

impairment, including, but not limited to, suffering from NSF/NSD, which may have caused permanent effects, and which may continue in the future to cause her physical effects and damage which will affect her throughout her lifetime, and may lead to death.

40. Further, as a direct and proximate result of her being administered Omniscan, Plaintiff suffered significant mental anguish and emotional distress and will continue to suffer physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

41. Plaintiff has also incurred medical expenses and other economic harm and will continue to incur such expenses in the future, as a direct and proximate result of her being administered Omniscan.

**COUNT I**  
**Strict Products Liability**  
**Defective Manufacturing**

42. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

43. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Omniscan.

44. The Omniscan manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk of injury and death.

45. As a direct and proximate result of Plaintiff's being administered Omniscan as manufactured, designed, sold, supplied and introduced into the stream of commerce by

Defendants, she has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

**COUNT II**  
**Strict Products Liability**  
**Design Defect**

46. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

47. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Omniscan.

48. The Omniscan manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect.

49. The foreseeable risks associated with the design or formulation of Omniscan, include, but are not limited to, the fact that the design or formulation of Omniscan is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

50. As a direct and proximate result of Plaintiff's being administered Omniscan as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, she has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

**COUNT III**  
**Strict Products Liability**  
**Defect Due to Inadequate Warning**

51. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

52. The Omniscan manufactured and supplied by Defendants was defective due to inadequate warning or instruction because Defendants knew or should have known that the product created significant risks of serious bodily harm and death to consumers and they failed to adequately warn consumers and/or their health care providers of such risks.

53. The Omniscan manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm and death from the administration of Omniscan, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

54. As a direct and proximate result of Plaintiff's being administered Omniscan as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, she has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

**COUNT IV**  
**Strict Products Liability**  
**Defect Due to Nonconformance with Representations**

55. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

56. Defendants are the manufacturers, designers, distributors, sellers or suppliers of Omniscan and made representations regarding the character or quality of Omniscan, including representations that Omniscan was safe.

57. The Omniscan manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product.

58. Plaintiff and/or her health care providers justifiably relied upon Defendants' representations regarding the Omniscan at the time it was administered to him.

59. As a direct and proximate result of Plaintiff's being administered Omniscan and the reliance on Defendants' representations regarding the character and quality of Omniscan, she has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

**COUNT V**  
**Strict Products Liability**  
**Defect Due to Failure to Adequately Test**

60. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

61. Defendants advised consumers and the medical community that Omniscan was safe for use. Defendants failed to adequately test Omniscan with respect to its use by consumers with renal insufficiency.

62. Had Defendants adequately tested the safety of Omniscan for use by consumers with renal insufficiency and disclosed those results to the medical community or the public, Plaintiff would not have been administered Omniscan.

63. As a direct and proximate result of Defendants' failure to adequately test the safety of Omniscan and as a direct and proximate result of Plaintiff's being administered Omniscan as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

**COUNT VI**  
**Strict Liability in Tort**

64. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

65. Defendants used and controlled toxic gadolinium for injection in humans.

66. Gadolinium is highly toxic, inherently dangerous, and ultrahazardous to humans.

67. Defendants allowed and directed that toxic gadolinium be used and injected in humans.

68. As a direct and proximate result of Defendants' use and control of toxic gadolinium, toxic gadolinium was injected and released into the body of Plaintiff and she has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

69. Defendants are strictly liable for Plaintiff's injuries, damages and losses.

**COUNT VII**  
**Negligence - Highest Possible Duty of Care**

70. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

71. Because gadolinium is highly toxic and inherently dangerous and ultrahazardous to humans, Defendants had a duty to exercise the highest possible degree of care in the design, manufacture, sale and/or distribution of Omniscan into the stream of commerce, including the duty to assure that their product did not pose a significantly increased risk of bodily harm and adverse events.

72. Defendants failed to exercise the highest possible degree of care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, and distribution of Omniscan into interstate commerce in that Defendants knew or should have known that the product was inherently dangerous and ultrahazardous to humans and caused such significant bodily harm or death and was not safe for administration to consumers.

73. Defendants also failed to exercise the highest possible degree of care in the labeling of Omniscan and failed to issue to consumers and/or their health care providers, adequate warnings of the risk of serious bodily injury or death due to the use of Omniscan.

74. Despite the fact that Defendants knew or should have known that Omniscan posed a serious risk of bodily harm to consumers and was inherently dangerous and ultrahazardous to humans and particularly those with renal insufficiency, Defendants

continued to manufacture and market Omniscan for administration to magnetic resonance imaging and arteriography patients with renal insufficiency.

75. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise the highest possible degree of care as described above.

76. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

**COUNT VIII**  
**Negligence**

77. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

78. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of Omniscan into the stream of commerce, including a duty to assure that their product did not pose a significantly increased risk of bodily harm and adverse events.

79. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, and distribution of Omniscan into interstate commerce in that Defendants knew or should have known that the product caused such significant bodily harm or death and was not safe for administration to consumers.

80. Defendants also failed to exercise ordinary care in the labeling of Omniscan and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Omniscan.

81. Despite the fact that Defendants knew or should have known that Omniscan posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Omniscan for administration to magnetic resonance imaging and angiography patients with renal insufficiency.

82. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

83. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

**COUNT IX**  
**Breach of Express Warranty**

84. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

85. Defendants expressly warranted that Omniscan was a safe and effective paramagnetic contrast agent for magnetic resonance imaging/angiography.

86. The Omniscan manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to consumers when administered in recommended dosages.

87. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

**COUNT X**  
**Breach of Implied Warranty**

88. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

89. At the time Defendants designed, manufactured, marketed, sold, and distributed Omniscan, Defendants knew of the use for which Omniscan was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

90. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether Omniscan was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters.

91. Contrary to such implied warranty, Omniscan was not of merchantable quality or safe for its intended use because the product was unreasonably dangerous as described above.

92. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

**COUNT XI**  
**Fraud/Misrepresentation**

93. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

94. Defendants knowingly and intentionally made material, false and misleading representations to Plaintiff, her physician and to the public that Omniscan was safe for use and that Defendants' labeling, marketing and promotion fully described all known risks of the product.

95. Defendants' representations were in fact false, as Omniscan is not safe for use and its labeling, marketing and promotion did not fully describe all known risks of the product.

96. Defendants had actual knowledge based upon studies, published reports and clinical experience that its product Omniscan created an unreasonable risk of serious bodily injury and death to consumers, or should have known such information.

97. Defendants knowingly and intentionally omitted this information in their product labeling marketing, and promotion and instead, labeled, promoted and marketed their product as safe for use in order to avoid monetary losses and in order to sustain profits in its sales to consumers.

98. When Defendants made these representations that Omniscan was safe for use, it knowingly and intentionally concealed and withheld from Plaintiff, her physician and the public the true facts that Omniscan is not safe for use in consumers with renal insufficiency.

99. Defendants had a duty to disclose to Plaintiff, her physician and the public that Omniscan was not safe for use in patients with renal insufficiency in that it causes NSF/NSD because it had superior knowledge of these facts that were material to Plaintiff and her physician's decision to use Omniscan.

100. Plaintiff and her physician reasonably and justifiably relied on the Defendants' concealment of the true facts and reasonably and justifiably relied upon Defendants' representations to Plaintiff and/or her health care providers that Omniscan was safe for human consumption and/or use and that Defendants' labeling, marketing and promotion fully described all known risks of the product.

101. Had Plaintiff and her physician known of Defendants' concealment of the true facts that Omniscan was not safe for human use, Plaintiff would not have been administered Omniscan.

102. As a direct and proximate result of Defendants' misrepresentations and concealment, Plaintiff was administered Omniscan and has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

**COUNT XII**  
**Negligent Misrepresentation**

103. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

104. Defendants, in the course of thier business profession, supplied Plaintiff and her physician with false information for guidance in their decision to use Omniscan.

105. The false information supplied by Defendants to Plaintiff and her physician was that Omniscan was safe and would not adversely affect Plaintiffs health.

106. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to Plaintiff and her physician.

107. The false information obtained and communicated by Defendants to Plaintiff and her physician was material and they justifiably relied in good faith on the information to their detriment.

108. As a result of the negligent misrepresentations of Defendants, Plaintiff suffered injuries, damages and losses as alleged herein.

**COUNT XIII**  
**Outrageous Conduct**

109. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

110. Defendants' concealment from Plaintiff and her physician that Omniscan was not safe for use was extreme and outrageous conduct in that such conduct is so outrageous in character and so extreme in degree that it goes beyond all possible bounds of decency and is atrocious and utterly intolerable in a civilized community such as the State of Pennsylvania.

111. As a direct and proximate result of Defendants' extreme and outrageous conduct, Plaintiff suffered severe emotional distress.

112. As a result of Defendants' outrageous conduct, Plaintiff suffered injuries, damages and losses as alleged herein.

**WHEREFORE**, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, loss of consortium, punitive damages and other non-economic damages in an amount to be determined at trial of this action;
2. Medical expenses, income, and other economic damages in an amount to be determined at trial of this action;
3. Pre- and post-judgment interest;
4. Attorneys' fees, expenses, and costs of this action as allowed by law; and

5. Such further relief as this Court deems necessary, just, and proper.

**JURY DEMAND**

Plaintiff hereby demands a trial by jury on all issues so triable.

Respectfully submitted this 3rd Day of April, 2008.

THE LEVENSTEN LAW FIRM, P.C.

By:\_\_\_\_/s/EP0405\_\_\_\_\_

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